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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/967,305	09/28/2001	Jennifer Richardson	07334-312001 / MPI2000-31	5199

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FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/967,305	RICHARDSON ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-79* is/are pending in the application.

4a) Of the above claim(s) *1-32, 35-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33,34 and 59-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant s submission filed on 10/04/04 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant adds new claims 59-79, which are related to claims 33-34 and are not new matter.

Accordingly, claims 33-34, 59-79 are being examined.

The following are the remaining rejections.

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH, NEW REJECTION

Claims 33-34, 59-79 are indefinite for the use of the language "a predetermined value" in claim 33, because one cannot determine the metes and bounds of the claimed invention.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION, NEW REJECTION

The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

Claims 34, 59-79 are rejected under 35 USC 112, first paragraph, as lacking an adequate written description in the specification.

Claims 34, 66-72, 74, 78-79 are drawn to a method for identifying agents for treating prostate cancer, comprising exposing to a test sample a nucleic acid molecule that "hybridizes to the alpha-methylacyl-CoA racemase mRNA comprising SEQ ID NO:3 under the hybridization conditions recited in claim 34", wherein the nucleic acid molecule comprises at least 260, 300, 400, 500, 800, 900 nucleotides.

Claims 59-65, 73, 75-77 are drawn to a method for identifying agents for treating prostate cancer, comprising contacting alpha-methylacyl-CoA racemase mRNA with a nucleic acid probe "comprising" at least 15, 20, 25, 30, 40, 50, 75 consecutive nucleotides of the "complement" of SEQ ID NO:3.

It is noted that the nucleic acid probe of claims 34, 66-72, 74, 78-79 encompasses sequences of unknown structure and function, provided they are at least 260, 300, 400, 500, 800, 900 nucleotides in length, and hybridize under the hybridization conditions recited in claim 34 via a common fragment to SEQ ID NO:3.

It is further noted that a complement could be a partial or full length complement, wherein a partial complement could share with SEQ ID NO:3 only a few nucleotides.

Thus a complement of SEQ ID NO:3 could be sequences of unknown structure and function, that share with SEQ ID NO:3 only a few nucleotides.

Further, due to the language "comprising", the nucleic acid probe of claims 59-65, 73, 75-77 encompasses sequences of unknown structure and function, that are attached to at least 15, 20, 25, 30, 40, 50, 75 consecutive nucleotides of the "complement" of SEQ ID NO:3, having unknown structure and function.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus,

> visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of a nucleic acid probe that hybridizes to SEQ ID NO:3, or a nucleic acid probe that comprises at least 15, 20, 25, 30, 40, 50, 75 consecutive nucleotides of the complement of SEQ ID NO:3, per Lilly by structurally describing a representative number of a nucleic acid probe that hybridizes to SEQ ID NO:3, or a nucleic acid probe that comprises at least 15, 20, 25, 30, 40, 50, 75 consecutive nucleotides of the complement of SEQ ID NO:3, or by describing structural features common to the members of the genus, which features constitute a substantial portion of the genus. Alternatively, per Enzo, the specification can show that the claimed invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

In this case, the specification does not describe a nucleic acid probe that hybridizes to SEQ ID NO:3, or a nucleic acid probe that comprises at least 15, 20, 25, 30, 40, 50, 75 consecutive nucleotides of the complement of SEQ ID NO:3, that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of any nucleic acid probe that hybridizes to SEQ ID NO:3, or a nucleic acid probe that comprises at least 15, 20, 25, 30, 40, 50, 75 consecutive

nucleotides of the complement of SEQ ID NO:3, other than SEQ ID NO:3, nor any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses a single nucleic acid molecule consisting of SEQ ID NO:3, this does not provide a description of a nucleic acid probe that hybridizes to SEQ ID NO:3, or a nucleic acid probe that comprises at least 15, 20, 25, 30, 40, 50, 75 consecutive nucleotides of the complement of SEQ ID NO:3, that would satisfy the standard set out in Enzo.

The specification also fails to describe a nucleic acid probe that hybridizes to SEQ ID NO:3, or a nucleic acid probe that comprises at least 15, 20, 25, 30, 40, 50, 75 consecutive nucleotides of the complement of SEQ ID NO:3, by the test set out in Lilly. The specification describes only a single nucleic acid molecule consisting of SEQ ID NO:3. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of a nucleic acid probe that hybridizes to SEQ ID NO:3, or a nucleic acid probe that comprises at least 15, 20, 25, 30, 40, 50, 75 consecutive nucleotides of the complement of SEQ ID NO:3, that is required to practice the claimed invention. Since the specification fails to adequately describe the product that is used in the claimed method, it also fails to adequately describe the claimed method.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT

Rejection under 35 USC 112, first paragraph of claim 34 pertaining to lack of enablement for a method for identifying agents for treating prostate cancer, using a nucleic acid molecule that hybridizes to the alpha-methylacyl-CoA racemase mRNA comprising SEQ ID NO:3 under the hybridization conditions recited in claim 34, remains for reasons already of record in paper of 08/30/04.

New claims 59-79 are rejected for the same reasons of record.

Applicant argues that claim 34 has been amended to specified stringent hybridization and wash conditions, and that a nucleic acid molecule that hybridizes to racemase mRNA under stringent conditions is a probe that is sufficiently specific for racemase mRNA to identify racemase mRNA.

Applicant's arguments set forth in paper of 06/04/04have been considered but are not deemed to be persuasive for the following reasons:

Claims 34, 66-72, 74, 78-79 are drawn to a method for identifying agents for treating prostate cancer, comprising exposing to a test sample a nucleic acid molecule that hybridizes to the alpha-methylacyl-CoA racemase mRNA comprising SEQ ID NO:3 under the hybridization conditions recited in claim 34, wherein the nucleic acid molecule "comprises at least" 260, 300, 400, 500, 800, 900 nucleotides.

Claims 59-65, 73, 75-77 are drawn to a method for identifying agents for treating prostate cancer, comprising contacting alpha-methylacyl-CoA racemase mRNA with a nucleic acid probe "comprising" at least 15, 20, 25, 30, 40, 50, 75 consecutive nucleotides of the "complement" of SEQ ID NO:3.

It is noted that the nucleic acid probe of claims 34, 66-72, 74, 78-79 encompasses sequences of unknown structure and function, provided they are at least 260, 300, 400, 500, 800, 900 nucleotides in length, and hybridize under the hybridization conditions recited in claim 34 via a common fragment to SEQ ID NO:3.

It is further noted that a complement could be a partial or full length complement, wherein a partial complement could share with SEQ ID NO:3 only a few nucleotides. Thus a complement of SEQ ID NO:3 could be sequences of unknown structure and function, that share with SEQ ID NO:3 only a few nucleotides.

Further, due to the language "comprising", the nucleic acid probe of claims 59-65, 73, 75-77 encompasses sequences of unknown structure and function, that are attached to at least 15, 20, 25, 30, 40, 50, 75 consecutive nucleotides of the "complement" of SEQ ID NO:3, having unknown structure and function.

Applicant has not taught how to make numerous nucleic acid probes with unknown structure for use in the claimed method. Further, the probes would not be specific and would also hybridize to unknown sequences, even under the stringent hybridization conditions recited in claim 34.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

November 04, 2004